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APPLICATION NUMBER

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WEADOCK

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EXAMINER

ART UNIT PAPER NUMBER

3738

DATE MAILED:

05/11/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on Sept. 8, 1999

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-18 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

Best Available Copy

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Applicant is reminded of his responsibility to notify the USPTO of any litigation pertaining to this reissue application.

The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Claims 13-18 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

Present claims 13-18 are improper for a reissue application because they attempt to recapture subject matter surrendered in order to overcome a prior art rejection. Specifically, during the pendency of the patented file 08/289,790, the language "filled with fluid which solidifies and is crosslinked to form" and "said material being insoluble at a pH of about 7.4" was

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added in order to overcome a prior art rejection. Therefore, it is improper to attempt to recapture this subject matter via claims 13-18 in the present reissue application.

With regard to the late information disclosure statement filed in the patented file May 6, 1996, these same references have been considered in the information disclosure statement of the present reissue application.

Claim Objections

Claim 17 is objected to because of the following informalities:

The language "said chemical solution" lacks antecedence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of

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the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 7 and 15 recites the broad recitation collagen, and the claim also recites specific types of collagen such as collagen I, etc. which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 13 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Jernberg (US 5,290,271) wherein the microparticles are the precipitated composition as claimed; see the entire document.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman Jr. et al (US 5,197,977) in view of Herweck et al (US 5,192,310). Hoffman Jr. et al meets the claim language by disclosing a vascular graft which is sealed by a precipitate of collagen and solidified by crosslinking but fails to disclose the expanded PTFE substrate as claimed; see the entire document. Herweck et al, however, teaches that it was known to the art to use expanded PTFE as a substrate or implant material in order to provide an inert graft material; see the entire document. Hence, it is the Examiner's position that it would have been obvious to use the Herweck et al base material or substrate as the substrate of Hoffman, Jr. et al so that the inert and advantageous properties envisioned by Herweck et al can be utilized in the Hoffman, Jr. et al invention.

Claims 1-8 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alonso (US 5,037,377) in view of Herweck et al (US 5,192,310). Alonso discloses many types of porous substrates for use therewith but fails to disclose the use of expanded PTFE, which inherently has the node and fibril structure recited in claims 1 and 13, as the substrate material; it is noted that soluble collagen of Alonso is made insoluble by crosslinking it and that it is insoluble at a 7.4 pH because 7.4 is the pH of the crosslinking solution and the crosslinking solution does not dissolve the collagen material; see the entire document. Herweck et al, however, teaches that it was known to use expanded PTFE as a substrate and graft material in order to provide an inert

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graft material; see the entire document. Hence, it is the Examiner's position that it would have been obvious to use the Herweck et al base material or substrate for the base or substrate of Alonso so that inert and advantageous properties envisioned by Herweck et al can be utilized in the Alonso invention.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alonso and Herweck et al as applied to claims 1-8 and 13-18 above, and further in view of Okita (US 4,193,138). Alonso fails to make the substrate hydrophilic as required. Okita, however, teaches that it was known to render substrate of porous grafts hydrophilic in order to improve the antithrombic nature of the substrate. Hence, it is the Examiner's position that it would have been obvious to render the Alonso substrate hydrophilic, as taught by Okita, in order to make the substrate less thrombogenic once the collagen is bioresorbed.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alonso, Herweck et al and Okita as applied to claim 11 above, and further in view of Hoffman (US 5,034,265). Okita teaches coating the expanded PTFE substrate with a hydrophilic polymer but fails to disclose using glow discharge plasma deposition to affect this coating. Hoffman, however, teaches that it was known to coat similar implants with a plasma deposition method. Hence, it is the Examiner's position that it would have been obvious to coat the substrate of Alonso with the polymer of Okita using plasma deposition for the same reasons that Hoffman utilizes the same type coating.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin, can be reached on (703) 308-1065. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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